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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,839	08/22/2003	Mark L. Witten	12241-022-999	2057

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EXAMINER	
HEARD, THOMAS SWEENEY	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
10/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,839	WITTEN ET AL.	
	Examiner	Art Unit	
	THOMAS S. HEARD	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/23/2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-68 and 70-93* is/are pending in the application.

4a) Of the above claim(s) *43,47,48,50,55-67,70,74,75,77 and 82-93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42,44-46,49,51-54,68,71-73,76 and 78-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Applicants Amendments to the claims received on June 23rd, 2009 is acknowledged. The text of those sections of Title 35 U.S. Code not included in the action can be found in the prior office action. Rejections or objections not addressed in this office action with respect to the previous office action mailed December 23, 2008 are hereby withdrawn.

Claim(s) 42-68 and 70-93 are pending. Applicants have amended claim(s) 42, 68, 70-93. Claims 43, 47, 48, 50, 55-67, 70, 74, 75, 77, 82-93 are withdrawn. Claims 42, 44-46, 49, 51-54, 68, 72, 73, 76, 78-81 are hereby examined on the merits.

Claim Rejections - 35 USC § 102

Applicant's have amended Claim 42 to "a subject who has been exposed to cigarette smoke," overcoming the rejection. The anticipation rejection over Claims 42, 45-46, 49, 51,52, 68, 69, 72, 73, 76, 78, and 79 is withdrawn.

Claim Rejections - 35 USC § 112

Applicant's amendments to Claims 42 and 68 have overcome the 112 First paragraph Written Description and Enablement rejection. The rejections have been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

For the purpose of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. V. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held in accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976);In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

Claims 42, 44-46, 49, 51-54, 68, 71, 72, 73, 76, 78-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robledo R.F. et al, "NK1-receptor activation prevents hydrocarbon-induced lung injury in mice," Am. J. Physiol. Lung Mol. Physiol (1999), 276:229-238, made of record in the previous office action, in view of Harris D.T. et al, "Protection from JP-8 Jet Fuel Induced Immunotoxicity by Administration of Aerosolized Substance P," Toxicology and Industrial Health, Vol. 13 (1997), pages 571-588 (from Applicant's IDS), Dorr; Robert T., US Patent 4,657,032, and Lee L.L. et al,

"Polycyclic Aromatic Hydrocarbon Present in Cigarette Smoke Cause Bone Loss in an Ovarictomized Rat Model, Bone Vol. 30 (2002), pages 917-923.

The instant invention is drawn to a method of ameliorating damage caused by cigarette smoke by the administration of a Substance P analog, that of Applicant's elected species of [Sar^9, Met $(O_2)l^{11}$]-substance P. The administration is by inhalation (aerosol) in the concentration ranges of 0.1 μM to 10 μM. The population is that of a subject who has been exposed to main-stream cigarette smoke.

Robledo R.F. et al teaches the administration of the Substance P analogue [Sar^9, Met $(O_2)l^{11}$] via aerosol inhalation. The hydrocarbon air mixture was administered to a group of mice who were also administered the Applicant's elected Substance P analogue by inhalation (aerosol) for the treatment regime. Further, the aerosol concentration of the [Sar^9, Met $(O_2)l^{11}$]-substance P was 5 μm readable upon Claims 45 and 46, 51, 52, 68, 69, 71-73, 78, 79, and 80.

The difference between what is taught by the prior art and that instantly claimed is that while Robledo R.F. et al teaches the administration of Substance P and Applicant's elected species to a subject that has not been exposed to hydrocarbons from cigarette smoke, Robledo R.F. et al does not teach the administration of Substance P to a subject who has been exposed to hydrocarbons from cigarette smoke.

Harris D.T., et al teaches the administration via aerosolization of Substance P for the protection of JP-8 jet fuel. It is taught that the JP-8 jet fuel is composed of aromatic

and aliphatic hydrocarbons (see introduction on page 572) and the administration of Substance P could exert its effect by the inhibition of lung damage (see page 586).

Dorr et al teaches drug administration through the filer of a cigarette which would be drawn into the lungs of the smoker as the smoke from the cigarette is pulled into the mouth, see entire Patent reference which is readable on Claims 54, 80, and 81.

Lee L.L. et al teaches that cigarette smoke is composed of over 4000 different chemical, to which aryl hydrocarbons are found in the smoke stream of the burning tobacco. It is further taught that these hydrocarbons are also found in the emissions of diesel fuel.

It would have been obvious to one of ordinary skill in the art to administer Substance P as taught by Robledo R.F. et al, to those who have been exposed to hydrocarbon inhalation as taught by Harris et al for the benefit of ameliorating the lung damage caused by inhaled hydrocarbons, as cigarette smoke is full of hydrocarbon. One would have been motivated to administer Substance P given the teaching of the compounds known ability to reduce the effects of the damage caused by the inhalation of hydrocarbons, the major component of cigarette smoke and tar from the cigarette. One would have had a reasonable expectation of success in using the invention as claimed since the administration of Substance P via aerosolization has already been taught in the prior art and the reason for such administration was for the correction of the damage that is caused by inhaled hydrocarbon material.

It would also have been obvious to one skilled in the art at the time of invention to determine all operable and optimum component of amounts of Substance P to dose via

aerosol, because these component amounts and ratios are an art-recognized result-effective variable that is routinely determined and optimized in the medicinal composition arts. Also note that Clams 49 and 76 are claims to results that are the effective outcome of practicing the method of Claim 42 and 68 for example, and must logically follow from the administration of Applicant's elected species. From the teachings of the references supra, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, and the invention as claimed, is rejected under 35 U.S.C. 103(a).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Prior art contained in the reference of record can be applied in the next office action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure

outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Thomas S. Heard** whose telephone number is **(571) 272-2064**. The examiner can normally be reached on 9:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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